DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION	**APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW. DISPLAY, OR DEVICE**	Form Approved: 0910-0025 Execration Date October 31, 2000 See Page 4 for OMB Statement. **DOCKET NUMBER**

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this Application in accordance with 21 CFR 1010.4.

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INSTRUCTIONS

1. Check all applicable boxes and type or print the requested Information.
2. Submit an original and four (4) copies.
3. Mail your application to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1-23, 12420 Parklawn Drive, Rockville, MD 20852.
4. Enter Document Number if assigned.

1. NAME OF COMPANY: **The Amphitheater**

2. ADDRESS OF COMPANY (Include ZIP CODE) (IF P.O. Box is used, include actual street address also.)
1609 E. 7th Ave Tampa, FL 33605

3. NAME AND TITLE OF RESPONSIBLE PERSON	4. TELEPHONE NO. (Include area code)	5. DATE OF SUBMISSION
John Santoro General Manager	**1 (813) 248-2331**	3-15-2000

6. **The applicant requests the variance to be in effect for a period of 2 years from the date of issue.**
(In general, the Agency will approve a Variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)

7. **PRODUCT DESCRIPTION AND USE**

a. **LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)**
The Amphitheater

b. **PRODUCT FOR WHICH A VARIANCE IS REQUESTED**
[ ] A LASER DISPLAY DEVICE
[ ] A PROJECTOR FOR A LASER LIGHT SHOW
[X] A LASER LIGHT SHOW
[X] OTHER (Specify)___

c. [ ] PROJECTORS ARE INTENDED FOR RESALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. **PRODUCT IS INTENDED FOR USE IN A**
[X] PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE
[X] THEATER
[X] HOTEL/MOTEL BALLROOM OR MEETING ROOM
[X] STORE DISPLAY
[X] TRADE SHOW OR CONVENTION
[X] DISCOTHEQUE OR NIGHT CLUB
[X] PAVILION
[X] INDOOR ARENA
[X] OUTDOOR ARENA
[X] MUSEUM
[X] OUTDOOR UNENCLOSED AREA
[X] OTHER (Specify)___ **AS PER NOTIFICATION**

e. **PRODUCT IS INTENDED TO BE USED**
[ ] AT ONLY ONE (Fixed) Location
[X] AT A VARITY OF (Tour) LOCATIONS
[X] OTHER (Specify) **AS PER NOTIFICATION**

f. **PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION**
[X] MORE THAN 15 DAYS
[X] MORE THAN 5 BUT NOT MORE THAN 15 DAYS
[X] LESS THAN 5 DAYS

g. **TOUR IS INTENDED TO RUN FOR**
[ ] MORE THAN 6 MONTHS
[ ] 1-6 MONTHS
[ ] LESS THAN 1 MONTH
[X] NOT APPLICABLE (Not a tour)
[X] OTHER (Specify)_____**AS PER NOTIFICATION**

h. **PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS**
[X] FRONT SCREEN PROJECTIONS
[X] REAR SCREEN PROJECTIONS
[X] HOLOGRAPHIC DISPLAYS
[X] MULTIPLE REFLECTIONS/DIFFRACTION EFFECTS
[ ] AUDIENCE SCANNING (Also includes scanning any accessible uncontrolled areas)
[X] REFLECTIONS FROM STATIONARY MIRRORS OR MIRRORED SURFACES (Beam Matrices)
[X] STATIONARY IRRADIATION OF ROTATING MIRRORS BALLS, ETC.
[X] SCANNING IRRADIATION OF ROTATING MIRROR BALLS. ETC.
[X] FIBER OPTIC PROJECTIONS
[X] FOG, SMOKE, OR OTHER SCATTERING ENHANCEMENT EFFECTS
[X] OTHER (Specify) **AS PER NOTIFICATION**

8. **LASER RADIATION LEVELS**

LASER MEDIUM (Ar, He-Ne, ect.)	WAVE LENGTHS (nm)	PEAK POWER (Watts)
KRYPTON	**400 - 700 nm**	**8 WATTS**
ARGON / YAG	**457.9 - 532 nm**	**40 WATTS**
ARGON / KRYPTON (WHITE	**457.9 - 676.4 nm**	**20 WATTS**

9. **IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE.**
SCANNING BANDWIDTH FROM DC TO 5 kHz MODULATION IN BOTH COLOR AND INTENSITY FROM DC To 100 kHz.

10. **REASON FOR REQUESTING VARIANCE**
[X] COMPLIANCE WITH THE LIMITS OF 21 CFR 1040-11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT
[ ] OTHER OR ADDITIONAL EXPLANATION (Specify)

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VAR1

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICATION STANDARD

[X] IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS SPECIFIED IN 21 CFR 1040.11(c0

[ ] IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) AS FOLLOWS:

11. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

[X] LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11(c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.

[ ] OTHER OR ADDITIONAL ADVANTAGES (describe and explain)

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply, in item 14 "Remarks, " justify any boxes not checked, using additional sheets as necessary, State any other means of radiation that will be used.)

a. [X] ALL LASER PRODUCTS, SYSTEMS, SHOWS, AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 21 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDE PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.

b. [X] EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED, NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.

c. [X] SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.

d. [X] LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS 1 WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO STAND OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS 1 OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c).

e. [ ] ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.

f. [X] ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AND PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR (S). THE OPERATOR(S) WILL:

(1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;

(2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND

(3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.

g [X] THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.

h. [X] THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS) WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT, BEAM LIMITERS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.

I. [ ] LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.

J. [X] IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10(h), THE MANUFACTURE OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CDRH PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOW.

k. [X] THE REQUIREMENTS OF 21 CFR 1002.30(a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP, ALIGNMENT, TESTING. AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10, THE CONDITIONS OF THIS VARIANCE, AND THE CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z 136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER QUIVALENT USER CONSENSUS STANDARD AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS, LASER RADIATION RES WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELL, BARRIERS, GUARDS, ECT.) THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SET-UP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT ARES, THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION, THE APPROVAL LETTER, CURRENT PROCEDURES, AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES.

l. [X] ADVANCE WRITTEN NOTICE WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL, STATE, AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED, AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT TO THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATIONS WILL BE MADE, BUT NOT NECESSARILY BE LIMITED, TO;

(1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ-312), 8757 GEORGIA AVE., SILVER SPRINGS, MD 20910, PROVIDING THE INITIAL AND CLOSING DATES FOR FIXED INSTALLATIONS AND THE ITINERARY FOR MOBILE SHOWS. IN ADDITION, UNLESS ALL ASPECTS OF SUCH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED, EACH NOTICE WILL INCLUDE DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.

(2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E.., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCES, ECT.) . IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND ANY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO, IF THESE CONDITIONS CAN NOT BE MET, THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SHOW.

(3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHING THEIR JURISDICTIONS, ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14. REMARKS

The Amphitheater WILL ONLY USE EQUIPMENT FROM COMPANIES MANUFACTURING CERTIFIED PROJECTORS. FROM TIME TO TIME RENTAL EQUIPMENT WILL BE REQUIRED. IN THIS EVENT WE WILL ONLY RENT CERTIFIED EQUIPMENT FROM COMPANIES A PROPER RENTAL VARIANCE.

SAMPLE: PRECISION PROJECTION, LAS VEGAS LASERS, & CERTIFIED PROJECTORS MANUFACTURED BY The Amphitheater.

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading, or incorrect in any material way. I have submitted and will submit all reports by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE:	16. NAME (type or print)	17. TITLE
	John Santoro	**Generial Manager**

REPORT ON LASER LIGHT SHOW OR DISPLAY*

PART 1
IDENTIFICATION OF MANUFACTURER

1.1 Manufacturer

a. Name of light show manufacturer: **The Amphitheater**

b. Address: Street **1609 E. 7th Ave**
City **Tampa**
State **FL** Zip Code **33605**

c. Area code and telephone **(813) 248-2331**

1.2 Importer (if applicable):

a. Name of importer

b. Address: Street
City
State Zip Code

c. Area code and telephone ( )

1.3 Name, signature, and title of person preparing this report

a. Name: **Robert J Ruhl**

b. Signature: 

c. Title: **Safety Consultant**

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*
Information on laser projectors is to be submitted using "Guide for Preparing Initial Reports and Model Change Reports on Lasers and Products Containing Lasers," HHS Publication FI)A 86-8259.

PART 2

IDENTIFICATION OF REPORT

2.1 Is this report pursuant to paragraph (c) of 21 CFR 1002.61?
(x) Yes ( )No

2.2 This report is

(x) an initial report

( ) a model change report

( ) a supplemental report

2.3 If this is a supplemental report, give CDRH accession number and date of the initial or model change report that it supplements.

Accession number:_____

Date:_____

2.4 Date of this report: _____

PART 3

SHOW NAME

3.1 What is (are) the name(s) or the light show or display?

PART 4
VARIANCE

4.1 Attach a copy of your variance application (FDA Form 3147) or, if approved, your variance approval letter (or variance number).

See Attachment to Part 4.1

PART 5

PROJECTION EQUIPMENT

5.1 List each projector used in the light show by manufacturer, model number or other designation, and CDRH accession number for the projector if known.

Manufacturer	Model or designation	CDRH accession number
Las Vegas Laser	**LT-1 000**	**91V-0509**

PART 6

SHOW VENUE

6.1 The laser light show or display takes place in:

(x) Planetarium or other dome projection structure

(x) Theater

(x) Hotel/Motel ballroom or meeting room

(x) Store displays

(x) Trade show or convention

(x) Discotheque or nightclub

(x) Pavilion

(x) Indoor arena

(x) Outdoor arena

(x) Museum

(x) Outdoor unenclosed area

(x) Other (specify) **AS PER NOTIFICATION**

6.2 The laser light show or display takes place:

(x) at only one (fixed) location

(x) at a variety of (tour) locations

(x) Other (specify) **AS PER NOTIFICATION**

PART 7

SHOW LOCATIONS, DATES, TIMES

7.1 Give specific location(s), date(s), and time(s) for the show, if known.*

AS PER NOTIFICATION

PART 8

SHOW EFFECTS PRODUCED

8.1 The laser light show uses the following laser effects:

__x__ front screen projections

__x__ rear screen projections

__x__ holographic displays

__x__ multiple reflection/diffraction effects

_____ audience scanning, including scanning any accessible, uncontrolled areas

__x__ reflections from stationary mirrors or mirrored surfaces

__x__ stationary irradiation of rotating mirror balls or other mirrored shape

__x__ scanning irradiation of rotating mirror balls, etc

__x__ fiber optic projections

__x__ fog, smoke, or other scattering effects

__x__ other(specify) AS PER NOTIFICATION

*see footnote 1 at the end of this Guide

PART 9

DIAGRAMS AND DRAWINGS OF SHOW VENUE

9.1 Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. Include in the drawings the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirrors, mirror balls, display screens (or other targets), and beam termination points.

Show the direct and reflected laser radiation beam paths. Provide the laser radiation levels in each beam including the wavelengths, peak and average power, and scan parameters (if scanned) for the worst case from a human access point of view. Be sure the drawings indicate the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions, and any direct or reflected beams into audience or performer locations.

Drawings attached. **(x)** Yes ( ) No (If "No," explain why)

SEE ATTACHMENT TO PART 9.1

PART 10
LASER RADIATION LEVELS

10.1 Describe how each of the laser radiation levels, indicated above, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculations that were made.

Description and calculations enclosed? **(x)** Yes ( )No.

Our use of lasers and power levels for any display would fall within general light show industry normal levels and the capability of our existing equipment.

EXAMPLE'S: Based on laser light show display and practices.

1. Beam Effects from 2 to 40 Watts

2. Screen effects from ½ to 5 Watts

All other effects would be at minimum power levels.

PART 11

SCANNING SAFEGUARDS

11.1 Will there be audience scanning* from any of the planned effects?
( )Yes **(x)**No

11.2 Do any of the planned effects require laser radiation (direct or scanned beams) to be viewed by operators, performers, or employees?
( )Yes **(x)** No

If the answer to either of the above questions is yes; describe how the radiation levels that reach into audience areas are maintained within the limits of Class I. If Class I limits are maintained by scanning, your description must include details of the required scan failure safeguard, including a discussion of the means of detection of the scanning, the theory of the operation of the scanning safeguard, and its speed of response.

Description attached? ( ) Yes **(x)** No (If "No," explain why)

NOT APPLICABLE

11.3 Will any laser radiation greater than Class I STRIKE BUT NOT BE VIEWED by operators, performers, or other employees?

( )Yes **(x)** No

If "Yes," describe, in detail, the operation of the scan failure safeguard or other means which will prevent exposure to beams exceeding Class II. If a scan safeguard is used, include a discussion of the detection of scanning, the theory of operation, and the speed of response of the safeguard. If other means are used, such as pressure pads or infrared beams, describe in detail as well.

Description attached? ( ) Yes **(x)** No (if "No" explain why)

NOT APPLICABLE

*see footnote 2 at the end of this Guide

PART 12

OPERATOR CONTROLS

12.1 Is the show under the continuous control of an operator? **(x)** Yes ( ) No

12.2 Does the laser operator perform tasks in addition to operation of the laser projector?

(x) Yes ( ) No (If "Yes," describe those tasks)

Equipment maintenance, equipment alignment, equipment set-up.

12.3 Can the operator see all the propagating beam paths, their terminations, and the audience at all times during the performance?

(x) Yes ( ) No (If "No, "explain how adequate surveillance is provided)?

12.4 Do any other personnel assist in providing surveillance of the laser display?
(x) Yes ( )No

If "Yes;" state number of persons, their identification, and how they assist in providing surveillance.
Information attached? **(x)** Yes ( ) No (If "No," explain why)

Operator's assistant, Staff from the laser show venue will be enlisted if necessary and if available, to assist the operator with observing effects the operator may not be able to see directly.

12.5 What qualifications are required of laser operators for your show?*

All operators will be familiar with laser hazards, safety regulations, .and have. no less than 4 weeks training.

* see footnote 3 at the end of this Guide

OPERATOR CONTROLS (Continued)

12.6 If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions?

(x) Yes ( )No ( ) Not applicable
(If "No, "explain alternate control)

12.7 How is this person designated? What are his or her other duties?

NOT APPLICABLE

12.8 What qualifications are required of this person?

NOT APPLICABLE

PART 13
PROJECTION EQUIPMENT CONTROLS

13.1 Are one or more readily accessible controls provided to immediately terminate laser radiation?
(x) Yes ( )No

Number of controls: 3

13.2 Describe the location of these controls and their operation relative to your show.
Control #1. Beam Attenuation on the projector
Control #2. Key Switch on the projector
Control #3. Key Switch on the laser power supply

PART 14

TEST PROCEDURES

14.1 Attach a copy of the written setup, alignment, and test procedures to be followed prior to the operation of the laser light show at each location (see sample checklist for laser light shows in Appendix).

Procedures attached? **(x)** Yes ( ) No (If "No," explain why)

SEE ATTACHMENT TO PART 14.1

14.2 When are these setup, alignment, and test procedures performed?

Before all shows

14.3 What laser radiation levels are used during setup, alignment, and checkout?
150 milliwatt Approximated

14.4 Is a record of the results of the setup, alignment, and test procedures maintained?
(x) Yes ( )No

If "No," explain how adequate quality assurance is maintained.

NOTE: Adequate record keeping would include, but not be limited to: (l). sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beams; (2) information on scanning patterns, velocity, and frequency; and (3) laser radiation levels used in each effect.

PART 15

NOTIFICATION PROCEDURES

15.1 What procedures are followed for notification of appropriate Federal (CDRH, FAA), State, and local agencies?

SEE ATTACHMENT TO PART 15.1

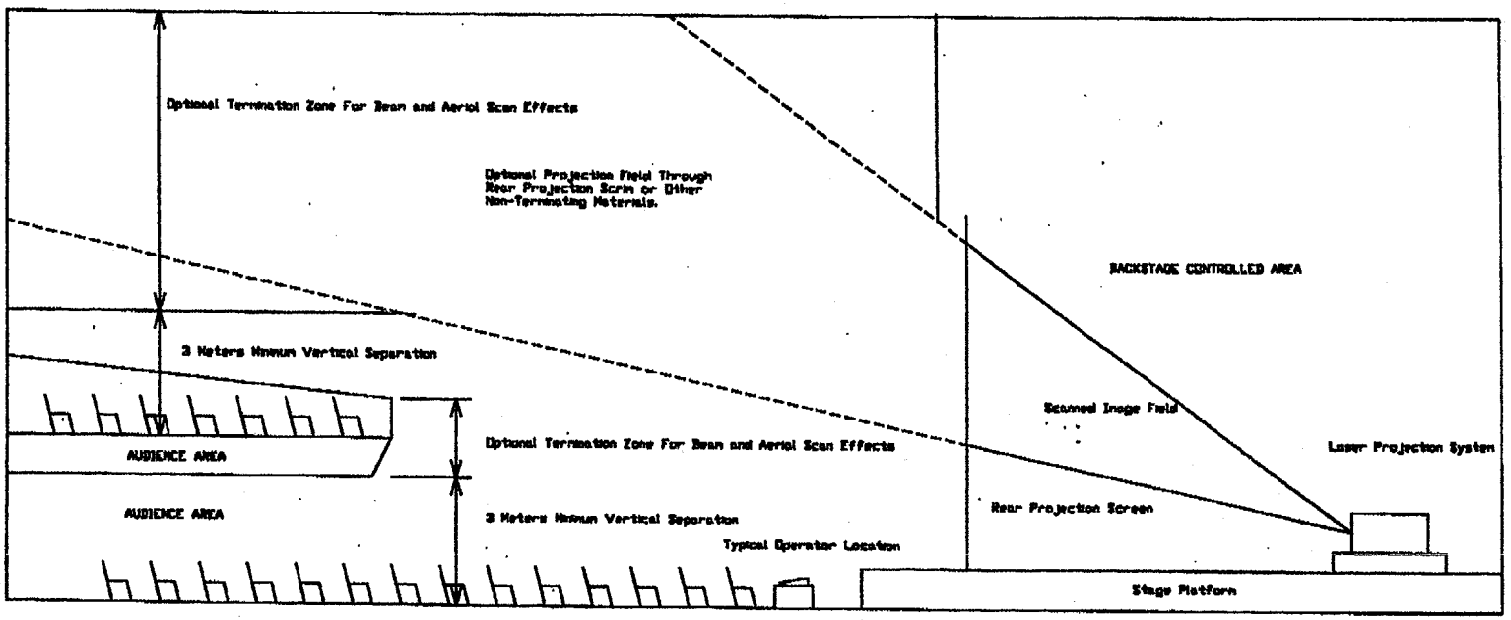
Procedures and/or form letters attached. **(x)** Yes ( ) No (If "No," explain. why)

15.2 What Federal, State, or local agencies are notified or 'would be notified? List of agencies attached: (x) Yes ( ) No (If "No," explain why)

SEE ATTACHMENT TO PART 15.2

Attachment to 9.1

TYPICAL INDOOR REAR PROJECTION CONFIGURATION - ELEVATION VIEW



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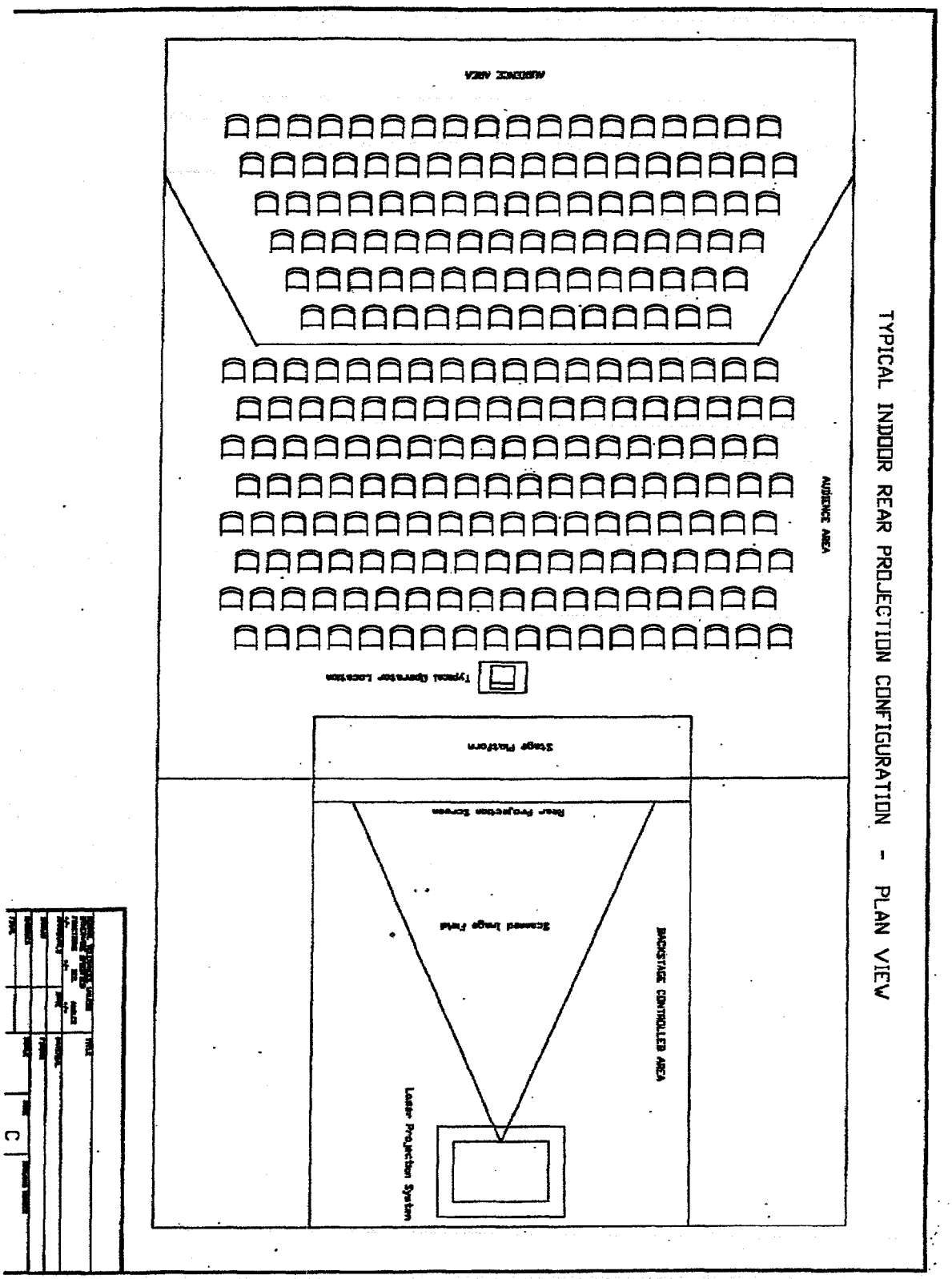
Attachment to 9.1



Attachment to Part 14.1

DAILY PERFORMANCE CHECK LIST

EQUIPMENT SETUP CHECK LIST

1.	All protective covers properly fit and secured	Yes [ ]	No [ ]
2.	All beam shutters operate properly	Yes [ ]	No [ ]
3.	Key Switch Functional	Yes [ ]	No [ ]
4.	Emission Indicator Functional	Yes [ ]	No [ ]
5.	Emission Delays Operating	Yes [ ]	No [ ]
6.	Interlocks Functional	Yes [ ]	No [ ]

PROJECTOR LABEL VERIFICATION

1.	Manufacturers' Certification	Yes [ ]	No [ ]
2.	Manufacturers' Identification label	Yes [ ]	No [ ]
3.	Warning Logotype	Yes [ ]	No [ ]
4.	Aperture Labels	Yes [ ]	No [ ]
5.	Light Show Certification	Yes [ ]	No [ ]

PROJECTOR HOUSING LABEL VERIFICATION

1.	Non-Interlock	Yes [ ]	No [ ]
2.	Laser Emission Indicator	Yes [ ]	No [ ]
3.	Defeatable Interlock	Yes [ ]	No [ ]
	Note: Refer to Manufacturer's Guide of locations		

ALIGNMENT

1.	Only qualified personnel no audience present	Yes [ ]	No [ ]
2.	Beam target alignment no audience present	Yes [ ]	No [ ]
3.	All targets secured in place	Yes [ ]	No [ ]
4.	Energize laser with shutters closed	Yes [ ]	No [ ]
5.	All power levels determined and recorded	Yes [ ]	No [ ]
6.	Check scan per test pattern	Yes [ ]	No [ ]
7.	Any problems found (if yes note on Daily performance)	Yes [ ]	No [ ]
8.	Were all potential CDRH violations resolved	Yes [ ]	No [ ]
9.	Was there a CDRH inspection	Yes [ ]	No [ ]
10.	Was there a State Inspection	Yes [ ]	No [ ]

Projector Model # _____

Projector S/N #_____

Date Inspected_____

System In Compliance---------- Yes [ ] No [ ]

Inspected By Sign: _____ Print: _____

Venue Name_____

Address_____

State_____ Zip_____

Attachment to Part 14.1

DAILY PERFORMANCE LIST
LASER LIGHT SHOW

Show Date:_____

Show Time:_____

Operator:_____

Venue Name:_____

Venue Location:_____

All items must be brought into a satisfactory state prior to the operation / or being checked off. If an item fails to meet, performance standards consult your supervisor. Do not attempt to run any show with any deficiency in performance standards. Include power levels, and remedies for any potential CDRH violations use reverse side if necessary.

Attachment to Part 15.1

STATE NOTIFICATIONS

Most states require notification concerning shows taking place within their borders. Requirements for notifications vary widely so it is wise to check with the proper authority. To reach the proper authority contact:

Sean Boyd (301) 594-4654

The responsibility to contact the state authority is that of the Manufacturer The Amphitheater

For the following states: California, Nevada, Washington, Idaho, Montana, Arizona, Hawaii, and Alaska contact

Gary Zaharek, EOS FDA (HFR-PA1530) 96 N Third Street, San Jose, CA 95112, (408) 291-7549 Fax (409 291-7228

For Texas:

Texas Department of Health, Bureau of Radiation Control, 1100 West 49th St., Austin, TX 78756-3199 Phone (512) 834-6688 Fax (512) 834-6690

Attachment to part 15.1

Notification to State, Federal, and Local, Officials will be no less then 2 weeks whenever possible. FAA Notifications will be 4 to 6 weeks. In the case of less then one-(1) week notice, notification will be sent by fax to CDRH and appropriate authorities.

Attachment to Part 15.2

For States: ME, NH, MA, NY, CT, RI

Max Lager, EOS
FDA (HFR-NE25)
1 Montvale Avenue
Stomeham, MA 02180.3542
(617) 279-1675 ext. 154
279-1742.Fax

For States: NJ, DE, MD, VA, TN, NC, SC, GA, FL, PR, MS, LA

Dennis Butcher, EOS
FDA, (HFR-SE18)
(404) 347-3576 ext. 5259
347-4349 Fax

For States: PA, WV, KY, OH, IL, MI, WI, MN, ND, SD

James E, Frye, EOS
FDA, (HFR-MA450)
1141 Central Parkway
Cincinnati, OH 45202
(513) 684-3505
684-2905 Fax

For States IA, MO, AR, NE, KS, TX, WY, CO, NM, UT

Tom Goertz
FDA, Southwest Region (HFR-SW14)
7920 Elmbrook, Suite 102
Dallas, TX 75247
(204) 655-8100 ext. 141
655-8130 Fax

For States AZ, Southern California

Ralph L, Kirch, Engineer
FDA, (HFR-PA2530)
4615 E, Elwood Street, Room 200
Phoenix, AZ 85040
(602) 379-4595 Ext. 224

Backup for Los Angeles

Serrah Namini, EOS
FDA (HFR-PA2545)
18004 Skypark Circle, Suite 140
Irvine, CA 92714
(714) 836-2377
836-2878 Fax

For States: NV, MT, ID, OR, WA, AK,HI

Gary Zaharek, EOS
FDA (HFR-PA1530
96 N Third Street
San Jose, CA 95112
(408) 291-7549
291-7228 Fax

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1609 E. 7th Ave
Tampa, FL 33605

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Food and Drug Administration, Room1-23,
12420 Parklawn Drive
Rockville, MD 20852.